Dr Harald Enzmann
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Basel, October 22nd, 2018.

Subject: Withdrawal of Type II variation EMEA/H/C/004143/II/0014 for Tecentriq (atezolizumab)

Dear Dr Enzmann,

I would like to inform you that Roche Registration GmbH has taken the decision to withdraw the type II variation application to extend the use of Tecentriq in combination with bevacizumab, for the first-line treatment of patients with unresectable locally advanced or metastatic renal cell carcinoma (RCC) whose tumours have a PD-L1 expression ≥1%.

The withdrawal is based on IMmotion151 results that are not sufficient to support an extension of indication at this time. The study will continue as per protocol to the next analysis for overall survival.

This withdrawal does not have any impact on ongoing clinical trials with atezolizumab as monotherapy or in combination with other agents.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

Roche would like to sincerely thank the (Co-)Rapporteurs and EMA for the time dedicated to reviewing this application and the support provided during the procedure.

I agree for this letter to be published on the EMEA website.

Yours sincerely,
On behalf of Roche Registration GmbH.

Roche Registration GmbH
(registered in Germany
with registration numbe
[redacted]
[redacted]
Reply to
[redacted]

[redacted]

Senior Regulatory Program Manager

[redacted]

Regulatory Program Manager

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Reply to

[redacted]